PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
Fung, et al.

Application No.: 10/783,619
Filed: 02/20/2004

Confirmation No.: 7207

Title: ACTIVE INGREDIENTS PREPARATION AND SINGLE COMPOUND PURIFICATION FROM TRADITIONAL CHINESE HERBAL MEDICINE *FRUCTUS TRICHOSANTHIS* AND USES THEREOF

Examiner: MI, QIUWEN

Art Unit: 1655

Docket No: C1295-118-118

Customer No.: 40614

Submitted via EFS-WEB

BRIEF ON APPEAL

This is an appeal from the Final Office Action mailed July 24, 2008 in the above-referenced application, which was affirmed by an Advisory action mailed November 10, 2008. A notice of appeal was filed October 23, 2008 and Appellant hereby petitions to extend the time to file the Appeal Brief by 3 months.

REAL PARTY IN INTEREST

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RELATED APPEALS AND INTERFERENCES

None

STATUS OF CLAIMS

Claims 72-77, 80-91 and 94-100 are pending in the application. Among the pending claims, claims 83-86 and 97-100 are withdrawn and are not the subject of this

appeal, and claims 72-77, 80-82, 87-91 are finally rejected under 35 U.S.C. § 102 and are the subject of this appeal.
All other claims are canceled.

STATUS OF AMENDMENTS

An amendment was filed subsequent to final rejection but not entered by the Examiner.

SUMMARY OF CLAIMED SUBJECT MATTER

Claim 72, one of the two independent claims subject to this appeal, relates to a pharmaceutical composition which comprises an extract from one of two plants of the Trichosanthes genus. While being difficult to be defined in terms of its specific composition and structural features, the extract is defined by its function and by the manner it is prepared in the claims. Specifically, the extract is required to have an effect of inducing hemoglobin synthesis in the human K562 cells and, to have such an effect, the extract should be prepared by extracting the plant of the Trichosanthes genus with a 50%-70% ethanol solution to obtain a syrup (see paragraphs [0002] , [0021], [0026]-[0029], and [0102]).

Claim 87, the other independent claim subject to this appeal, relates to a pharmaceutical composition which comprises an extract from a plant of the Trichosanthes genus. The extract, similarly as in claim 72, being difficult to be defined in terms of its specific composition and structural features, is rather defined by its function and by the manner it is prepared in the claims. As the function limitation, the extract is required to have an effect of inducing hemoglobin synthesis in the human K562 cells and, to have such an effect, the extract should be prepared by extracting the plant of the Trichosanthes genus with a 50%-70% ethanol solution as the first step (see paragraphs referred above). Additionally, this claim requires a second extraction step to prepare the extract, that is, to extract the first extracted

syrup with a solvent having a polarity index less than the 50%-70% ethanol solution used in the first extraction step(see paragraph [0067]).

GROUNDS OF REJECTION TO BE REVIEWED

Rejection of claims 72-77, 80-82, and 87-91 grounded on 35 U.S.C. §102 as being anticipated by Iketani et al (the translated English version of JP 62108844A).

GROUP OF CLAIMS

With respect to the specific ground of rejection subject to this appeal, claims 72-77, 80-82, and 87-91 will stand and fall together. This grouping is for the purpose of efficiency of this appeal only and such grouping does not constitute an admission that the claims in the group are not each independently patentable in any other legal or administrative proceedings.

ARGUMENT

A. Claims 72-77, 80-82, and 87-91 Are Not Anticipated by Iketani Reference.

The Examiner's rejection of the claims under 35 USC §102 is apparently based on the belief that the extract of Iketani is the same extract claimed in the present invention and therefore would inherently anticipate the functional limitation recited in the claim.

Appellant respectfully submits that such a belief equaling the Iketani extract to the present invention defies common sense of a person having an ordinary skill in the art, who undoubtedly would know the phrase "like dissolves like," a basic principle of organic chemistry. Strongly polar compounds like sugars (e.g. sucrose) or ionic compounds, like inorganic salts (e.g. table salt) dissolve only in very polar solvents like water or an ethanol solution, while strongly non-polar compounds like oils or

waxes dissolve only in very non-polar organic solvents like hexane. The extract of the present invention is extracted with a polar solvents (50%-70% ethanol solution) and can only contain mostly polar ingredients. In contrast, the Iketani extract was made by extracting with ether three times (lines 2-5 of last paragraph on page 5) in the first extraction step and then again with ether in the second extraction step (line 4 of last paragraph on page 6). Ether, just like hexane, is a strong non-polar organic solvent and the extract using ether as solvent can only contain non-polar ingredients. Surely, the Iketani extract is an "oily substance" (last line on page 6, and line 11 of second paragraph on page 9). In terms of water solubility, comparing the present invention with Iketani is like comparing the sucrose with the waxes: they cannot be the same thing.

Because the Iketani extract is different from the present invention, it cannot expect to inherently have the function of the presently claimed subject matter, that is, the effect on hemoglobin synthesis in human K562 cells recited in the rejected claims.

Furthermore, the Iketani reference itself discloses the following facts which contradict the Examiner's assertion that the extract is the same as in the present invention:

(a) The Iketani reference specifically discloses that the extract there is an oily substance (last line on page 6, and line 11 of second paragraph on page 9), which as people having ordinary skill in the art would understand cannot be dissolved in a 50%-70% ethonal solution, while the extract of present invention is very polar can be dissolved in a 50%-70% ethonal solution.

(b) The Iketani reference specifically discloses that the extract contains an oily compound (1,3-ditricosanoyl-2-linoleoyl glycerol) (line 4 of paragraph 1 on page 13) which after being chemically converted to a more polar compound (tricosanoic acid) (paragraph 2 on page 13) possess an inhibitory effect on platelet aggregation (paragraph 2 on page 15). Therefore, the two extracts are *prima facie* different in terms of their biological effects: the inhibitory effect on platelet aggregation (the

Iketani extract) versus the stimulating effect on hemoglobin synthesis (the present invention).

B. Rejection Does Not Meet the Legal Standard about Functional Limitations

It is well established by the court that functional limitations are proper in patent claims and should be given patentable weight in determining anticipation. See *In re* Ludtke, 169 USPQ 563, 566 (C.C.P.A. 1971).

As taught by this Board in *Ex parte* Skinner, when there is reason for the Examiner to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, the Examiner has the authority to require an applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on, but "[n]evertheless, before an applicant can be put to this burdensome task, the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art." *Ex parte* Skinner, 2 USPQ 2d 1788 (B.P.A.I. 1987)(emphasis added) .

In this case, the Examine has failed to provide any evidence or scientific reasoning to establish the Examiner's belief is reasonable. On the contrary, as discussed in the foregoing, the rejection was made by relying on a belief that defies common sense of a person having ordinary skill in the art and runs contrary to a basic scientific principle. Furthermore, during the regular prosecution stage, the Examiner did not afford Appellant any opportunity to rebut the Examiner's unsupported assertion by making this completely new rejection final, which is clearly premature due to the nature of this rejection.

CONCLUSION

In view of the foregoing analyses, Appellant respectfully submits that the 102 rejection in this case is utterly improper because it is made based on an unsupported inherent anticipation theory, which flies in the face of a basic scientific principle. It is

respectfully submitted that the rejected claims should be found allowable by the Board. Reversal of the rejection of all the claims is earnestly solicited.

Respectfully submitted,
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APPENDIX:

EVIDENCE

None

RELATED PROCEEDINGS

None

CLAIMS ON APPEAL

72. A pharmaceutical composition comprising an extract from *Trichosanthes rosthornii Harms* or *Trichosanthes japonica Regal*, wherein said extract induces hemoglobin synthesis in human K562 cells and said extract is prepared by a method comprising the steps of:

(a) contacting *Trichosanthes rosthornii Harms* or *Trichosanthesjaponica Regal* with a first solvent consisting of an aqueous solution of from 50% to 70% ethanol to form a mixture;

(b) heating the mixture to form a liquor; and

(c) concentrating the liquor to form a first syrup.

73. The pharmaceutical composition of claim 72, wherein said method further comprises the step of:

(d) extracting the first syrup with a second solvent having a polarity index less than that of the first solvent to form a second syrup.

74. The pharmaceutical composition of claim 73, wherein said method further comprises the step of:

(e) purifying the second syrup to obtain a compound.

75. The pharmaceutical composition of anyone of claims 72-74, wherein the extract exhibits a major peak with a retention time of 7.935 min when analyzed by high performance liquid chromatography using a 4.6 x 250mm C4 column, a mobile phase

with 75% water and 25% acetonitrile/0.1% trifluoroacetic acid, at a flow rate of 2.0 ml/ min.

76. The pharmaceutical composition of anyone of claims 72-74, wherein the extract is prepared from the roots, stems, leaves, flowers, fruits, or seeds of *Trichosanthes rosthornii Harms* or *Trichosanthes japonica Regal*.

77. The pharmaceutical composition of anyone of claims 72-74, further comprising a pharmaceutically acceptable carrier or adjuvant.

80. The pharmaceutical composition of anyone of claims 72-74, wherein the second solvent is a lower alkanol, or a mixture of water and a lower alkanol.

81. The pharmaceutical composition of claim 72, wherein the second solvent is ethanol.

82. The pharmaceutical composition of claim 72, wherein step (b) is performed at a temperature ranging from 40°C to 80°C.

87. A pharmaceutical composition comprising an extract from a plant of Trichosanthes, wherein said extract induces hemoglobin synthesis in human K562 cells and said extract is prepared by a method comprising the steps of:

(a) contacting the plant with a first solvent consisting of an aqueous solution of from 50% to 70% ethanol to form a mixture;
(b) heating the mixture to form a liquor;
(c) concentrating the liquor to from a first syrup; and
(d) extracting the first syrup with a second solvent having a polarity index less than that of the first solvent to form a second syrup.

88. The pharmaceutical composition of claim 87, wherein the extract exhibits a major peak with a retention time of 7.935 min when analyzed by high performance liquid

chromatography using a 4.6 x250mm C4 column, a mobile phase with 75% water and 25% acetonitrile/0.1% trifluoroacetic acid, at a flow rate of 2.0 ml/min.

89. The pharmaceutical composition of claim 87 or 88, wherein the plant is *Trichosanthes rosthornii Harms* or *Trichosanthesjaponica Regal*.

90. The pharmaceutical composition of claim 87 or 88, wherein the extract is prepared from the roots, stems, leaves, flowers, fruits, or seeds of the plant.

91. The pharmaceutical composition of claim 87 or 88, further comprising a pharmaceutically acceptable carrier or adjuvant.

94. The pharmaceutical composition ofclaim 87 or 88, wherein the second solvent is a lower alkanol, or a mixture of water and a lower alkanol.

95. The pharmaceutical composition of claim 87 or 88, wherein the second solvent is ethanol.

96. The pharmaceutical composition of claim 87 or 88, wherein step (b) is performed at a temperature ranging from 40°C to 80°C.